510(k) SUMMARY, revised.

510(k) number: K030877

Submitted by: TriMed, Inc.
25768 Parada Drive
Valencia, California 91355
800-633-7221

Prepared by: Robert J. Medoff, MD
Contact person: Robert J. Medoff, MD (rmedoff@hawaii.rr.com)
Date prepared: December 29, 2003
Proprietary Name: TriMed Radial Bullet

Classification Name: Bone fixation plate

Common/Usual Name: TriMed Radial Bullet
(other names reserved for future sites of application)

Sample Predicate Devices:
TriMed small fragment clamp and buttress pin (510(k) K951303)
Distal radius plate (Hand Innovations)
Forte distal radius fixation plate (Zimmer)
TriMed Radial Pin Plate (TriMed)
Dorsal Nail Plate (Hand Innovations)
Flexible Intramedullary Nail System for metacarpal fractures (Hand Innovations)

Class: II, Sec. 888.3030 (PLATE, FIXATION, BONE)

Classification Panel: These devices are reviewed by an orthopaedic panel (888)

Product Code: HRS

 December 29, 2003

Description of the device:

The TriMed Radial Bullet is a bone fixation implant that is used as an aid to fracture fixation. All components of the implant are manufactured either from medical grade 316 stainless steel or medical grade titanium-vanadium-aluminum alloy. Dimensional characteristics of the devices have been provided in enclosure 1 of the 510(k) submission as well as attachment A of the first 510(k) supplement.

Intended use of the Device:

The TriMed Radial Bullet is intended for use as an aid to fracture healing. The implants are inserted across a fracture site and aid in stabilization of the bone fragments until bone healing occurs. The implant design includes a tip that is placed up against the subchondral bone of the tip of the radial styloid to prevent loss of radial length during fracture healing. The TriMed Radial Bullet may be used with bone screws, washers, locking bone screws and/or locking fixation pegs **of the same material**. The principal site of application is along the radial column in the context of distal radius fixation for treatment of fractures or osteotomies. Other sites of application may be reserved for future use.

Technological characteristics:

The TriMed Radial Bullet has identical technical characteristics to existing bone fixation plates that are in common use. Sample existing implant literature is supplied with enclosure 5 of the 510(k) application, and material specification sheets are supplied with enclosure 6 of the initial 510(k) application as well as attachment C of the first 510(k) supplement.

Indications for use:

The TriMed Radial Bullet is indicated for:

1. Fixation of fractures or non-unions of the distal radius
2. Osteotomies of the distal radius to correct malunion

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2004

TriMed, Inc.
C/o Robert J. Medoff, M.D.
159 Ku'ukama Street
Kailua, Hawaii 96734

Re: K030877
Trade/Device Name: TriMed Radial Bullet
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: December 29, 2003
Received: January 7, 2004

Dear Dr. Medoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number: K030877
Supplement 2 – Attachment 2A

Indications for Use

The TriMed Radial Bullet is indicated for:

1. Fixation of fractures or non-unions of the distal radius

2. Osteotomies of the distal radius to correct malunion

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

Division of Reconstructive
Neurological Devices

K030877